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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,353	07/14/2004	Enrico Anthony Antonini	1580 WO/US	7589
Jeffrey S Boone Mallinckrodt Inc 675 McDonnell Boulevard PO Box 5840 St Louis, MO 63134				
7590 06/26/2009			EXAMINER AULAKH, CHARANJIT	
			ART UNIT 1625	PAPER NUMBER
			MAIL DATE 06/26/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/501,353

**Applicant(s)**

ANTONINI, ENRICO ANTHONY

**Examiner**

Charanjit S. Aulakh

**Art Unit**

1625

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 and 24-163 is/are pending in the application.
- 4a) Of the above claim(s) 44-67, 71-150 and 155-163 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22, 24-43, 68-70 and 151-154 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/19/07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. According to paper filed on Feb. 13, 2009, the applicants have filed a RCE.
2. Claims 1-22 and 24-163 are pending in the application. Claims 44-67, 71-150 and 155-163 remain withdrawn as being directed to non-elected inventions.

### ***Response to Arguments***

3. Applicant's arguments filed on Oct. 16, 2007 have been fully considered but they are not persuasive regarding objection for containing non-elected subject matter. The election of group I was without traverse and therefore, claims must be amended to read upon the elected group. In regard to obviousness and written description rejections, the examiner agrees with the applicants arguments and therefore, these rejections are now withdrawn.

### ***Priority***

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119(e), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the

reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional

information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

#### NEW GROUNDS OF REJECTION

#### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-22, 24-43, 68-70 and 151-154 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson ( J. of Chromatography, cited on applicant's form 1449 ).

Peterson discloses rapid reversed-phase chromatography for separation of narcotic alkaloids including morphine. Peterson meets all the limitations of instant claims except that Peterson does not mention non-polar stationary phase, polar mobile phase and ratio of a mass of the stationary phase media to the narcotic alkaloid. However, non-polar stationary phase and polar mobile phase are well known to be part of the reverse phase chromatography and the ratio of a mass of the stationary phase media to narcotic alkaloid is within the routine skill of an artisan in this field. Therefore, it would have been obvious to one skilled in the art to separate morphine using reverse phase chromatography with reasonable expectation of success.

8. Claims 1-22, 24-43, 68-70 and 151-154 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vandenberghe ( Therapeutic Drug Monitoring ).

Vandenberghe discloses paired-ion reversed-phase chromatography for separation of morphine. Vandenberghe meets all the limitations of instant claims except that Vandenberghe does not mention non-polar stationary phase, polar mobile phase and

ratio of a mass of the stationary phase media to the narcotic alkaloid. However, non-polar stationary phase and polar mobile phase are well known to be part of the reverse phase chromatography and the ratio of a mass of the stationary phase media to narcotic alkaloid is within the routine skill of an artisan in this field. Therefore, it would have been obvious to one skilled in the art to separate morphine using reverse phase chromatography with reasonable expectation of success.

9. Claims 1-22, 24-43, 68-70 and 151-154 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matantseva ( Khimiya prirodnykh Soedinenii ).

Matantseva discloses reversed-phase chromatography for separation of narcotic alkaloids including morphine ( see english translation ). Matantseva meets all the limitations of instant claims except that matantseva does not mention non-polar stationary phase, polar mobile phase and ratio of a mass of the stationary phase media to the narcotic alkaloid. However, non-polar stationary phase and polar mobile phase are well known to be part of the reverse phase chromatography and the ratio of a mass of the stationary phase media to narcotic alkaloid is within the routine skill of an artisan in this field. Therefore, it would have been obvious to one skilled in the art to separate morphine using reverse phase chromatography with reasonable expectation of success.

10. Claims 1-22, 24-43, 68-70 and 151-154 are objected for containing non-elected subject matter.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is

(571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charanjit S. Aulakh/  
Primary Examiner, Art Unit 1625